HFI-35 9/9/98

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
T2085M
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-71

September 10, 1998

Donald F. Decker, President
Cosmetic Concepts, Inc.
5205 NW 163rd Street
Miami, Fl 33014

Dear Mr. Decker:

During an inspection of your drug and cosmetic manufacturing facility located in Miami, Florida on June 25, 26 and 29, 1998, our investigator, Jennifer Donzanti, documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's manufacturing of sunscreen products, causing these drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Sunscreens are drugs because of their claims to provide minimal to total protection from the sun's harmful rays.

The inspection revealed that there is no assurance that your sunscreen products meet applicable standards of identity, strength, quality and purity in that you have failed to comply with CGMPs including:

> Failure to test each batch of finished product for the identity and strength of the active ingredients. [21 CFR 211.165(a)]
>
> Failure to validate the manufacturing process for any of the sunscreens produced. [21 CFR 211.110(a)]
>
> Failure to conduct appropriate stability studies to support the lack of an expiration date on your sunscreen products. [21 CFR 211.137(h)]

You have also failed to establish that any of your "waterproof" sunscreens conform to that specification.

Your company received a previous Warning Letter (copy attached) dated September 24, 1993, which included two of the three GMP deviations listed above and the lack of "waterproof" testing. You responded to that Warning Letter (copy attached) on October 22, 1993, stating additional laboratory equipment had been ordered and GMP procedures were being rewritten, which should be completed by December 1993. Despite these assurances, the current inspection disclosed most of the deviations noted in the 1993 inspection have not been corrected.

The above description of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, any pending export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. The potential actions include seizure and/or injunction.

You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be sent to Kendall W. Hester, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

Douglas D. Tolen,
Director, Florida District

Enclosures
1. Warning Letter dated September 24, 1993
2. Cosmetic Concepts letter dated October 22, 1993